EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., Plaintiff,	)	CIVIL ACTION
v	)	NO. 20-753-LPS
ANNORA PHARMA PRIVATE LIMITED, Defendant.	)	NO. 21-196-LPS
BIONPHARMA INC., Intervenor.	)	

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Wilmington, Delaware
Friday, January 28, 2022
Telephonic Oral Argument

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BEFORE: HONORABLE LEONARD P. STARK, Judge

APPEARANCES:

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and
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serially extend the expiration of the patent coverage. That is not the case here. Here Azurity has one patent family Epaned, all of the patents expire together.

Notably, Annora failed to cite a single case that finds that the interest in having a low cost generic on the market outweighs the well-establish interest in protecting the incentives for our patent system.

As the Federal Circuit has repeatedly noted, including in Sanofi vs. Apotex 470 F.3d 1368, "There is a significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents."

That public interest favors maintenance of the status quo and entry of an injunction until a post trial decision can be rendered here. Accordingly, all the factors weigh in favor of Azurity and a preliminary injunction should be granted.

THE COURT: All right. Thank you. A few questions for you, Ms. Devine.

One of the general themes, and you've already addressed it, but I want to make sure I fully understand you. One of the general themes of the defendant here seems to be you all told me there would be horrible repercussions for your client if I did not grant a preliminary injunction to stop the launch of Bionpharma. I did not grant such a

preliminary injunction and your client has survived and, arguably, even thrived nonetheless. I understand some of the particular circumstances that happened with Bionpharma and presumably those precise circumstances would not occur again, but why shouldn't I conclude as a general matter your client will find a way to survive and this is just, you know, crying wolf a second time?

MS. DEVINE: Thank you, Your Honor. So there are a couple of reasons why the harm was stemmed from Bionpharma's launch. One being that Bionpharma had not qualified an additional supplier and lost its supplier, so the ongoing harm when we were before Your Honor in November ceased, to a certain extent, shortly thereafter because CoreRx chose to stop supplying Bionpharma; so that was an event that happened that did extend the harm.

Azurity did suffer irreparable harm as a result of Bionpharma's activities. And as Mr. Patel details, that harm is ongoing and still impacting the company. That it was stemmed through factual developments post our preliminary injunction is what affected things.

So I would doubt -- it's an unusual circumstance of Bionpharma, I would doubt that we would have the same situation with Annora that they would somehow lose their supply. But, you know -- so we doubt that we would be able to stem it in that same way.

and convincing evidence that these claims are invalid. I'm not.

All I am holding is that there's at least persuasive evidence of invalidity on the grounds that I have identified. And any language I may have used that seems broader than that is unnecessary. I do think that these may well be very strong defenses, but I don't have to make a conclusion on that, and I'm not making a conclusion on that.

Turning back, just briefly, to enablement. There's always an opinion from the defendant's expert that at least some number of inoperable embodiments are captured in the broad claims of the '868 patent and that, for this reason as well, undue experimentation would be necessary in order for the person of skill in the art to understand the full scope of what is actually enabled and claimed.

This is additional persuasive evidence that is sufficient to support my finding that the plaintiff has not met its burden to show a likelihood of success on the merits with respect to the claims of the '868 patents on which the motion is based.

So for all of those reasons, Azurity has failed to demonstrate a likelihood of success on the merits.

Let me turn, more briefly, to irreparable harm. In my view, Azurity has also failed to show irreparable harm, if -- as I am doing, I'm denying its motion for

preliminary injunction.

Azurity identifies a number of types of harms that might under other circumstances support a finding of irreparable harm. The parties here are direct competitors. This is a small -- or Azurity is a small specialty drug manufacturer. And Epaned, the product at issue in this litigation, is its flagship product and the defendant -- and the product is likely going to be substituted for Epaned.

As of today, there's market exclusivity. We heard, you know, late-breaking information that perhaps that will change, independent of my decision, as a result of the New York litigation between Bionpharma and CoreRx, its supplier. But as of today, it is true that Epaned is the only product in a ready-to-use liquid enalapril market.

The plaintiff has evidence that it will be harmed from the introduction into the market of a lower priced generic competitor. Annora's generic is obviously unauthorized and would, almost certainly, if introduced exert a downward pressure on the price of Epaned. And Azurity has said that it intends to launch its own authorized generic, which will also exert downward pressure.

I should be clear, Azurity has said if this motion is denied and if Annora does in fact intend to launch, then Azurity intends to launch its authorized generic. And even if ultimately further litigation were to

remove Annora's competitors product from the market, it would be difficult, I recognize, for the Epaned market price to go back to the higher price it's currently at. And that's true whether or not Azurity launches its authorized generic, but certainly all the more true, that is all the more difficult, if Azurity launches its authorized generic.

Azurity argues that it's going to have to scale back its education efforts related to its products and lose sales of its other products if it can't get its foot in the door as easily with its Epaned product. And also talks of -- and there's evidence for all those things, I recognize, loss of research and development opportunities, the possibility of employee layoffs, potential harm to the plaintiff's reputation and, perhaps, loss of access to funding.

All these things there's support for in the record, they all, I think, are harm, but the plaintiff has failed to persuade me on this record that any of those, individually or in combination, under the circumstances here constitute harm that would be irreparable.

One reason for Azurity's failure is the evidence with respect to what occurred in connection with Bionpharma's launch of it generic version of Epaned. The record appears to show that Azurity was not irreparably harmed by that launch and has fully recovered from it. That

is despite me, as the presiding judge in the Bionpharma case, having heard that essentially all the harms forecast now in this case, with respect to the pending motion here, would occur and would be irreparable were I to deny the preliminary injunction to stop Bionpharma's launch. I then denied that motion, Bionpharma launched and here we are months later, and I do not believe that Azurity has been irreparably harmed.

Now, two things: One, the record of all of that is fair for me to consider, much of it is in the record in this case. But beyond that, no one has argued I can't consider the Bionpharma situation. And I could take judicial notice of it as well.

But, second, I do want to emphasize, I recognize the circumstances are quite different here than in Bionpharma. I presume that Annora does not have the same supplier that Bionpharma did. And I'm sure it's unlikely that the parent or holder of some amount of equity of Azurity is going to go out and acquire or acquire some equity in whoever Annora retains as its supplier; and that fact pattern is unlikely to be repeated here.

But the important point to me is I don't know what will happen in the absence of granting the requested preliminary injunction, but I have real world experience with Azurity, real world experience with Azurity that it can

survive the launch of a generic, even when it told me that it would be irreparably harmed. At bottom, and most pertinently, Azurity just simply has not demonstrated that the harms it forecasts will befall it from a denial of its motion today will occur and will be irreparable.

In reaching that conclusion, I would also add that any alleged harms are likely quantifiable and monetarily compensable. This appears to have been true of the impact on the market from Bionpharma's launch of its unauthorized generic.

For example, Azurity's CEO and expert used data repositories to show the impact the Bionpharma generic had on Epaned's market share and price. And I have no reason to think that the same type of exercise cannot be undertaken after Annora's launch, if it turns out that Annora ultimately does not prevail on the merits and then is liable for damages to Azurity; I believe we will be able to calculate those damages with reasonable certainty.

The speculated loss of R&D opportunities, reduced sales of other products, layoffs and the other harms I listed before, in the context of this case I think Azurity can be compensated for these harms with a money judgment, probably a large money judgment. And, again, these are the same types of harms that were predicted to be both unavoidable and irreparable were Bionpharma to launch, but

that turned out not to be a correct prediction.

I'll add if it -- I have no reason to doubt that what I was told happened in the New York litigation this morning by counsel. It did in fact happen. If all of that means it's more likely that the status quo soon is going to be that there is a Bionpharma generic drug in this marketplace, that makes the plaintiff's failing to show irreparable harm for my denial of today's motion all the more glaring, but my decision is not based on that.

I imagine plaintiff is correct that there will be more litigation in that case, the New York case. And so I think that my decision is fully warranted, even on the assumption that Bionpharma won't be back in the market soon. But if Bionpharma will in fact be on the market soon, then it's even more difficult for the plaintiff to show irreparable harm from the introduction of a second unauthorized generic competitor than it would be to show for just one. And, so, that would only strengthen the basis of my decision.

Bottom line is Azurity has not met its burden to show that it will suffer irreparable harm in the absence of granting extraordinary relief of a preliminary injunction.

I'm not addressing balance of harms or the public interest, it's not necessary. The plaintiff has failed to met its burden on the first two required elements